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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	MAIL STOP AF
Guido Moruzzi)	
Application No.: 09/530,361)	Group Art Unit: 1744
Filing Date: April 28, 2000)	Examiner: MONZER R CHORBAJI
Title: METHOD AND APPARATUS FOR)	
STERILIZING A PACKAGING SHEET)	Confirmation No.: 5394
MATERIAL)	
)	
)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed concurrently with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheets (no more than five pages are provided.)

Respectfully submitted,

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Date: January 25, 2007

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I. Overview

In the final Office Action dated September 25, 2006, the Examiner has maintained the rejections under 35 U.S.C. § 102(b) and 103(a) over various U.S. patent documents set forth in the Office Action dated March 30, 2006. Prior to this, in the Amendment and Reply filed February 28, 2005 in connection with a request for continued examination, Applicants explained why the claims as amended were both distinct and patentably non-obvious over cited art including all but one currently cited reference. The Examiner did not respond to Applicants' arguments directly, but rather asserted that Applicants' arguments were moot in view of the newly stated grounds of rejection. OFFICE ACTION DATED MARCH 30, 2006 at 15, item 9. Applicants provided further explanation of the distinguishing features of the presently claimed invention over the prior art including the newly cited reference in the Reply filed by Applicants on June 30, 2006. The Examiner's response to the arguments in the Reply filed by Applicants on June 30, 2006 is concisely stated on the last two pages of the present final Office Action. OFFICE ACTION DATED SEPTEMBER 25, 2006 at 14-15.

Applicants respectfully submit that the Examiner has misapprehended the differences between the presently claimed invention and the prior art as being only differences in "manner of operation." *Id.* at 14, last paragraph. However, contrary to the Examiner's implication, the pending claims do in fact recite distinct distinguishing structural features, particularly in the required arrangements of elements, that also would have been non-obvious in view of the cited art at the time the application was filed.

The present claims recite a novel and non-obvious arrangement of the elements of the claimed device and corresponding methods for practicing the invention, which is a direct reflection of the novel and non-obvious manner of operation of the present invention. Thus, the recited structural arrangement and the manner of operation are conceptually intertwined. The specification explains and Applicants have provided evidence during the course of prosecuting this application that the reason the arrangement of elements recited in the claims would not have been obvious is that the manner of operation of the present invention is contrary to what was the accepted wisdom in the field at the time the invention was made.

It is true that the reason that the structure recited in the present claims would not have been obvious is that the manner of operation of the invention would not have been obvious. However, it is also true that the structures recited in the claims are sufficient to distinguish

the claimed invention from the cited art. For these reasons, as explained in detail below, the rejections should be withdrawn.

II. Rejection under 35 U.S.C. § 102(b)

Claims 15, 17, 26 and 29-31 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent Number 4,366,125 ("Kodera").

Kodera does not anticipate the claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990)(emphasis added). Thus, it is not enough for a reference to disclose the individual elements of a claimed invention, the reference must also disclose the arrangement of elements that is required by the claims. That is to say, a required arrangement of elements is an element in itself that must be disclosed by the prior art before a claim can be rejected.

Kodera discloses a device for sterilizing packaging material in which material is first wetted with H₂O₂, by a misting device B, is then exposed to UV radiation in device C while wet, and only after having been exposed to UV radiation while wet is the material dried in device D. Kodera at col. 5, lines 34-51 and FIG. 1.

Kodera does not teach a means for advancing packaging material continuously and sequentially (1) from a means for applying a hydrogen peroxide solution to a surface of a packaging material (2) through a means for directing a stream of air on the surface of said packaging material to remove substantially all but a residual or trace quantity of hydrogen peroxide and then (3) to a means for irradiating said packaging material with UV light having a UV wavelength between 200nm and 320nm as required by claims 15, 26 and 29.

The recitation of the means for advancing packaging material requires that the elements be arranged in the order recited along the path of advancement. Kodera does not teach or suggest the arrangement required by the claims. Kodera also does not teach or suggest the recited elements connected in sequence as required by claims 15 and 26.

Therefore, Kodera cannot anticipate claims 15, 26 and 29, because Kodera does not disclose the elements of the claimed invention arranged as required by the claims. Claims 17 and 30-31 depend from claims 15 and 29, so these claims are likewise not anticipated.

III. Rejections under 35 U.S.C. § 103(a)

A. Kodera and Castberg

Claims 18, 27, and 32 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kodera, *supra*, in view of U.S. Patent Number 5,744,094 ("Castberg"). Castberg is cited for disclosing an excimer lamp, which is an element of the apparatus recited in claims 18, 27 and 32. However, Castberg does not cure the deficiencies of Kodera that have already been described.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P. § 2143.

As discussed above, Kodera does not disclose the elements of the claimed invention arranged as required by the claims. Kodera explicitly teaches that exposure of film wetted with H₂O₂ to UV light produces a synergistic effect that was not observed when dry film was exposed to UV light. Kodera at col. 6, lines 18-42. Thus Kodera would have taught one of ordinary skill that packaging material should be wet with H₂O₂ when exposed to UV light for effective sterilization and would not have suggested a sequence of devices in which the H₂O₂ was removed prior to UV irradiation as required by claims 18, 27, and 32 as well as claims 15, 17, 26, 29, and 30-31. To do so would have gone against the accepted wisdom in the field that is represented by this disclosure by Kodera, and would not have been obvious. *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685 (Fed. Cir. 1986); Manual of Patent Examination Procedure § 2145.

Castberg discloses an excimer lamp, but does not reasonably suggest any modification in the arrangement of the devices taught by Kodera that would lead to the presently claimed invention. Therefore, the combination of Kodera and Castberg fails to teach or suggest the arrangement of elements required by the present claims and cannot establish a *prima facie* case of obviousness that is required to support the rejection. Manual of Patent Examination Procedure § 2142.

B. Koder a in combination with Doucette, DiGeronimo, Loliger and Lagunas-Solare.

Claims 4 and 28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Koder a, in view of U.S. Patent Number 3,513,627 (“Doucette”), U.S. Patent Number 4,494,357 (“DiGeronimo”) and U.S. Patent Number 3,692,468 (“Loliger”). Claims 2-3, 5 and 21-25 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Doucette, in view of Koder a, and DiGeronimo. Claim 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Doucette, in view of Koder a, DiGeronimo and Lagunas-Solare.

Claims 2-3, 4-6, 21-25 and 28 recite methods for sterilizing a packaging sheet material, comprising in the following order, applying a liquid solution of hydrogen peroxide to the surface of a packaging sheet material (or advancing the material through a bath of hydrogen peroxide); applying a stream of air to said packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging sheet material while retaining a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms present on said packaging sheet material; and thereafter irradiating the surface of said packaging sheet material with UV light.

Koder a discloses a method for sterilizing packaging material in which material is first wetted with H₂O₂, by a misting device, then exposed to UV radiation while wet, and only then is the material dried. Koder a at col. 5, lines 34-51 and FIG. 1. Koder a does not teach or suggest a method in which packaging material is wetted with H₂O₂, the H₂O₂ is substantially removed, and thereafter the packaging material is irradiated with UV light, in that order, as required by the rejected claims.

Doucette discloses a method in which material is wetted with germicidal liquid first using a sponge 51, then travels past a UV light source 85 while wet and then is wetted again in bath 63, exposed to additional UV light sources 87, wetted a third time in bath 73 and then dried using heater plates 89, after which the material may be exposed to UV light source 91 as it exits the apparatus. Doucette at col. 3, lines 24-65 and FIG. 1. Thus, in comparison to Koder a, Doucette teaches additional steps of wetting with germicidal liquid and exposure to UV radiation before drying the packaging material and optionally after drying the packaging material. However, Doucette does not teach or suggest a method in which the steps recited in

the rejected claims are performed according to the arrangement limitation required by the claims.

The Examiner has alleged that the Doucette method is the same as the method of the instant claims. OFFICE ACTION DATED SEPTEMBER 25, 2006 at 15. Applicants respectfully submit that the Examiner has failed to appreciate the structural distinction of the requirement that the claimed methods comprise the recited steps of the method “comprise in the following order” as recited in rejected claims, that is to say that the recitation of a method comprising the recited steps is structurally limited by the requirement that the steps that are recited occur in the order recited in the claims. Doucette teaches a method comprising an order of steps that is contrary to the order required by the present claims.

The order of the steps required by the claims is a direct reflection of the surprising discovery that such a method could provide the synergistic killing provided by irradiating material that has been wetted with H_2O_2 without the disadvantages of permitting the H_2O_2 to remain on the material. During the course of prosecution, ample evidence has been provided that it was surprising to the those of skill in the art that the methods and apparatus of the invention could work as effectively as has been demonstrated.

Neither Koderia nor Doucette or the combination thereof teach or suggest the order of steps required by the present claims. DiGeronimo, Loliger and Lagunas-Solare do not cure the defects of Doucette and Koderia. DiGeronimo is cited for allegedly teaching irradiating at 254 nm. Loliger is cited for allegedly teaching a peroxide bath temperature of 60 °C. Lagunas-Solare is cited for allegedly teaching the use of polychromatic light. DiGeronimo, Loliger and Lagunas-Solare, even when all are combined with Koderia and Doucette, fail to remedy the deficiencies of Doucette and Koderia.

Therefore, the cited prior art fails to support a prima facie case of obviousness because there is no teaching or suggestion leading to the arrangement of elements required by the claims; and the rejection cannot be maintained. Manual of Patent Examination Procedure § 2142.